Office Action Summary	Application No.	Applicant(s)	
	10/561,700	ODIDI ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2005 and 25 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *29, 30 and 46-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28 and 31-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *2 pages* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election Acknowledged

1. Applicants' election without traverse the invention of Group I encompassing claims 1-28 and 31-45 in the reply filed on January 15, 2008 is acknowledged. The restriction is made final.

Status of Application

2. Claims 1-48 are pending, claims 29, 30 and 46-48 are withdrawn and claims 1-28 and 31-48 are presented for examination on the merits. The following rejections are made.

3. **NOTE**: the rejections included in the previous office action sent out on October 24, 2007 are vacated and hereby replaced with the following objections and rejections. It is further noted that in Applicants reply, Applicant erroneously withdrew claims from a restricted group. Upon Applicants request, those 'withdrawn' claims are now included in this new grounds of rejection. This is a supplemental action.

Claim Objections

4. Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As of now, claim 25 is a duplicate of claim 24 from which it depends.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-28 and 31-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 10. Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims in both applications are drawn to compositions ultimately comprising:

i) a population of pharmaceutical substance;

ii) a population of basic substance;

iii) a population of an enterically coated pharmaceutical substance; and

iv) a population of an enterically coated basic substance.

And a third substance wherein components I and ii are released at a rapid rate and components iii, iv and the third substance are released at a slow rate. All other limitations are essentially

identical in teat the compositions contain the same active agents, disintegrants and enteric polymers and the composition of each is application is provided by capsule. Thus, the claims of copending application 10/861809 are not patentably distinct over the instantly claimed subject matter.

6. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. **Claims 1-28 and 31-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US 2002/0045646; of record, see IDS) and Bergstrand et al. (US 5817338; of record, cited in prior office action).**

9. Phillips is drawn to a composition for treating gastric disorders employing proton pump inhibitors (PPIs) in a pharmaceutically acceptable carrier. It is taught that the PPI can be any substituted benimidazole compound possessing H^+, K^+-ATPase inhibiting activity and being unstable to acid (i.e. acid labile). The composition of Phillips can be a powder, tablet, capsule and a two part tablet (see [0036]; see instant claims 1 and 31). It is taught that upon oral adminsitation of the PPI the drug may be absorbed into the bloodstream where the compound is eventually delivered to the acid secreting portion of the parietal cells of the stomach. The PPIs

included within the teaching of Phillips include omeprazole, lansoprazole and rabeproazole. It is note by Phillips that such PPIs are readily degraded under acidic conditions such as that of the stomach and a useful way to circumvent degradation is to include at least one buffering agent (i.e. basic substance). Basic substance include sodium bicarbonate, magnesium hydroxide and aluminum hydroxide (see [0054]; see instant claims 21 and 40). Moreover, the basicity of base used must be strong enough to elevate the pH of the stomach sufficiently to prevent significant degradation of the drug and to achieve ample bioavailability of the drug to induce a therapeutic effect.

10. Example VI teaches a multi-functional tablet comprising two discrete drug delivery systems i) free omeprazole and free sodium bicarbonate (rapid release) and ii) enterically coated omeprazole granules (slow release) (see [0176]; see instant claims 1-6, 10, 13, 18-21, 31). The tablet is taught to contain known binders and excipients (see [0176]; see instant claims 7 and 8). Such excipients include disintegrant such as cross-linked sodium carboxymethylcellulose (sodium croscarmellose) and fillers such as calcium lactate (see Example 1, B1 at page 10; see instant claims 8 and 28). The tablets of Example VI were formulated to deliver a bolus and a time-released dose of the PPI omeprazole (i.e. pulsed release, see instant claim 6). Upon ingestion of the tablet, the tablet dissolves, freeing the non-enteric coated base and omperazole into the stomach (see [0176], see instant claim 22). The basic substance increases the pH of the stomach, preventing the omeprazole from acidic degradation, and allows omeprazole to be absorbed by the parental cells of the stomach. Meanwhile, the enterically coated omeprazole is absorbed in the duodenum (see [0176]; see instant claim 23, 44 and 45). It's noteworthy that

four-hours post administration, the pH of the stomach is raised to an average of 7.1 (see Figure 3, see instant claim 24).

11. Although the teaching of Phillips motivates one to include an enterically coated omeprazole granule with free base and omeprazole, it still fails to teach what such an enterically coated granule is prepared from.

12. The teaching of Bergstrand is drawn to a pharmaceutical tablet dosage form containing omeprazole. The table of Bergstrand comprises a core substance which contains an acid susceptible substance such as omeprazole, followed by a first coating (separating layer), and then a second coating (an enteric coating) (see column 5, line 60 - column 6, line 35; see instant claims 13-17, 32+33). The separating layer includes alkaline gents to enhance the pH-buffering properties. This necessarily improves the stability of the acid labile omeprazole contained within the core as it prevents degradation of the drug during long periods of storage. Alkaline agents include compounds typically used in antacid formulations such as calcium hydroxide, sodium phosphate, and so on (see column 6, lines 20-30). The omeprazole granule of Bergstrand may be mixed with basic substances such as those discussed above (calcium hydroxide, etc.; see column 6, lines 20-30). The materials used for the enteric coating includes polyethylene glycol and polyvinyl acetate (see column 6, lines 45-55; see instant claim 27). As an example an omeprazole granule is found at Example 10.

13. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine the teachings of Phillips and Bergstrand because in doing so would result in a composition which possess a population comprising:

i) a population of base (i.e. sodium bicarbonate);

ii) a population of pharmaceutical substance (i.e. a PPI);

iii) a population of enteric coated pharmaceutical substance; and

iv) a population of enteric coated basic substance.

The significance of Phillips is that it teaches a multi-functional tablet compositions comprising

i) a population of base (i.e. sodium bicarbonate);

ii) a population of pharmaceutical substance (i.e. a PPI);

iii) a population of enteric coated pharmaceutical substance; and

The multifunctional tablet is manufactured to possess rapid an delayed-release functionalities (pulse release) wherein the pharmaceutical substance is present in both functionalities and the basic substance is present in the rapid release portion. Although the teaching of Phillips includes an enterically coated PPI population, it fails to set forth what it is comprised of. One of ordinary skill would be motivated to look to the art to see how to make an enterically coated PPI granule capable of effectively delivering the active substance to the body.

14. Bergstrand teaches PPI containing granules coated wit ha first separating layer followed by a second enteric polymer coating, wherein the enteric granule contains antacids such as sodium bicarbonate. Thus, one of ordinary skill would be motivated to include the granule of Bergstrand with the teaching of Phillips to arrive at an invention with the instantly claimed properties (see i-iv above). With respect to the recited properties such as rapid release of the rapidly released basic substance increasing the pH of the stomach to more than 4 and less than about 7 in less than 1 hour carries no patentable weight. Such a property would be obvious to optimize, as noted above, the stability of the PPIs as well as their pharmaceutical efficacy is dependent upon the pH of their local environment. If the pH of the stomach isn't rapidly

alkalinized, the drug will not be effective. Moreover, as both references are within the same general field of endeavor (delivery of antacids and PPIs), it follows that combination would be obvious and would result in a therapeutic composition having the properties of the instantly claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one ordinarily skilled in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
June 17, 2008

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615